



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/810,742 | 03/25/2004 | Clive Elson | 4245/2092 | 9666 |

29933 7590 03/19/2007
PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/19/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/810,742 | Applicant(s) ELSON ET AL. | |
| | Examiner Everett White | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-19 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2007 has been entered.

2. The amendment filed November 9, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 20-50 have been canceled;
- (B) Claims 1, 11 and 19 have been amended;
- (C) Comments regarding Office Action have been provided drawn to:
 - (I) 102(b) rejection, which has been maintained;
 - (II) 112 rejections, which have been withdrawn.

3. Claims 1-19 are pending in the case.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

5. The disclosure is objected to because of the following informalities: The formula " -C(C=O)-R-COG " which is set forth in the instant specification on page 2, lines 14, 16 and 17 is incorrectly written since the first carbon atom in the formula does not contain the required number of bonds to complete the formula. This formula may have been intended to be written as " -C(=O)-R-COG " as set forth on page 4, line 23 of the instant specification. Also see this incorrectly written formula on page 4, lines 7, 9 and 10 of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended Claim 11 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the compounds "N,O-carboxymethyl-N-succinylchitosan, N,O-carboxymethyl-N-citraconylchitosan, N,O-carboxymethyl-N-glutarylchitosan" disclosed in Claim 11 as subunits of the instantly claimed N-acylated chitinous polymer. These compounds are disclosed in the "Examples" of the instant specification, however, the examples do not refer to the compounds as subunits of the instantly claimed N-acylated chitinous polymer.

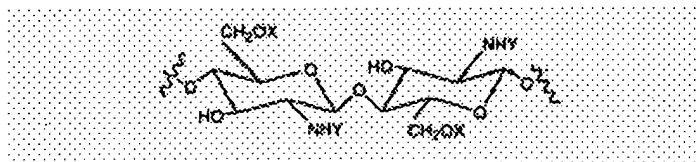
Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 102

8. Claims 1-8 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Elson (US Patent No. 5,888,988, already of record).

Applicants claim an N-acylated chitinous polymer, wherein said chitinous polymer is comprised of subunits of the formula:

Art Unit: 1623



wherein X is independently selected from hydrogen, $-(CH_2)_bCOG$, or $-(CH_2)_bCOOZ$ for each occurrence, provided that at least 10% of X groups on said polymer are $-(CH_2)_bCOOZ$ or $-(CH_2)_bCOG$; Y is independently selected from $-C(=O)-R-CO_2Z$, $-C(=O)-R-COG$, hydrogen, carboxyalkyl, acetyl, or a pharmaceutically acceptable salt thereof for each occurrence, provided that at least 1 % of Y groups on said polymer are $-C(=O)-R-CO_2Z$ or $-C(=O)-R-COG$; R is independently selected from the group consisting of alkyl, alkenyl, and aryl; b is 1-8; G is an agent or a pharmaceutically acceptable salt thereof; and Z is hydrogen, a cation, an agent, or a pharmaceutically acceptable salt thereof. Additional limitations in the dependent claims include the N-acetylated chitinous polymer, wherein said polymer is selected as N,O-carboxymethyl-N-succinylchitosan; the N-acetylated chitinous polymer, wherein said polymer is water soluble; the N-acetylated chitinous polymer, wherein said polymer is water soluble at pH's from about 1 to about 11; the N-acetylated chitinous polymer, wherein Z is an agent; the N-acetylated chitinous polymer, wherein said agent is a therapeutic agent; the N-acetylated chitinous polymer, wherein said therapeutic agent is an anti-cancer agent; the N-acetylated chitinous polymer, wherein said therapeutic agent is an agent for the treatment of a central nervous system disorder; the N-acetylated chitinous polymer, wherein said therapeutic agent is an anti-inflammatory agent.

The Elson patent discloses N,O-carboxymethyl chitosan (NOCC) compounds wherein the amino groups may be linked by a bridging reagent, for example, succinic acid, to provide succinylated NOCC (see column 7, last paragraph), which is the N,O-carboxymethyl-N-succinylchitosan set forth in instant Claim 11, which inherently comprises subunits of said N,O-carboxymethyl-N-succinylchitosan. The succinylated NOCC of the Elson patent anticipates the subject matter of Claim 1 when X in the formula thereof is $-(CH_2)_bCOOZ$, b is 1 and Z is hydrogen, which is representative of a carboxymethyl group; and when Y in the formula of instant Claim 1 is a $-C(=O)-R-CO_2Z$

Art Unit: 1623

group, wherein R is an alkyl or a $-(CH_2)_a-$ group, wherein a is 2, when Z is hydrogen, which is representative of a succinylated group. The preparation of NOCC linked with carbodiimide (EDC) and N-hydroxy-succinimide (NHS) groups is noted in Example 1 of the Elson patent. Table 1 in Example 1 of the Elson patent sets forth molar ratio of NOCC:EDC:NHS. Table 1 discloses a molar ratio for NOCC:EDC:NHS as 1:1:0.04 (see column 11), which indicates that the percent of X and Y groups present on the chitosan that are of the formula $-(CH_2)_bCOG$, or $-(CH_2)_bCOOZ$ for X and of the formula $C(=O)-R-CO_2Z$ or $-C(=O)-R-COG$ for Y, meet the minimum requirements set forth in the instant claims of X being at least 10% and Y being at least 1%. The Elson patent further discloses the NOCC group being linked to an active agent, wherein the active agent may be a peptide or protein (see column 9, line 3), which anticipates the subject matter of instant Claim 19. Also see column 9, lines 56-61, wherein the NOCC-active agent is used in methods for the prevention or minimization of infection and inflammation, debridement of wounds, topical application of active agents to wounds, absorption of exudates fluid, wound dressing and the like, which reads on the subject of Claims 15-18 wherein the agent thereof is a therapeutic agent, anti-cancer agent, anti-inflammatory agent or an agent for the treatment of a central nervous system disorder. The subject matter of Claims 12 and 13 regarding the solubility of the polymer in water is noted. However, this property of the polymer is not allowable over the succinylated NOCC of the Elson patent since the succinylated NOCC of the Elson patent contains identical subunits to the subunits of the N-acylated chitinous polymer of the instant claims and products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990), (See MPEP 2112.01). In view of the teachings of the Elson patent, the succinylated NOCC disclosed in the Elson patent anticipates the N-acylated chitinous polymer of the instant claims.

Allowable Subject Matter

9. Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim (with the exception of the R groups) and any intervening claims.

10. The Elson patent and other prior art of record does not teach or fairly suggest the N-acylated chitinous polymer of instant Claim 1 comprised of subunits of the formula disclosed in Claim 1, wherein the structures representing Y have R groups represented as aryl and/or R groups that comprises one or more heteroatoms.

Summary

11. Claims 1-8 and 11-19 are rejected; Claims 9 and 10 are objected to.

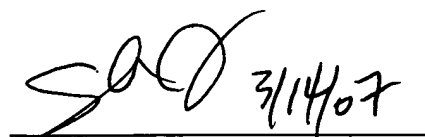
Examiner's Telephone Number, Fax Number, and Other Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


E. White


Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600